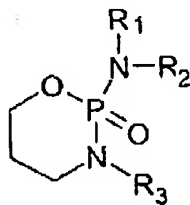


Application No. 10/529,273
Docket No. 01470-24439.US

CLAIM AMENDMENTS

Claims 1-26 (canceled).

27. (previously presented) A process for preparation of a low toxicity, stable oxazaphosphorine-containing composition comprising mesna, an etherified β -cyclodextrin, and an oxazaphosphorine antineoplastic of the formula



in which at least two of R_1 , R_2 , and R_3 independently are 2-chloroethyl and the remaining R radical is hydrogen, the process comprising the steps of:

- i) adding the oxazaphosphorine antineoplastic to an aqueous solution of an etherified β -cyclodextrin;
- ii) adding mesna as such or as an aqueous solution optionally containing an etherified β -cyclodextrin to the oxazaphosphorine solution of step (i); and
- iii) mixing the resultant aqueous solution and, optionally, making up the volume with water so that in the final composition, the oxazaphosphorine antineoplastic is from about 1 mg/ml to about 1000 mg/ml; the etherified β -cyclodextrin in the composition is about 1% to about 60% w/v; and the ratio of oxazaphosphorine antineoplastic to mesna is in the range of about 20:1 to about 1:2 on a weight basis.

28. (canceled).

29. (previously presented) A process as claimed in claim 27, wherein $R_1 = R_2 =$ chloroethyl, $R_3 =$ hydrogen, and the oxazaphosphorine antineoplastic is Cyclophosphamide.

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30. (previously presented) A process as claimed in Claim 27, wherein $R_1 = R_3 =$ chloroethyl, $R_2 =$ hydrogen, and the oxazaphosphorine antineoplastic is Ifosfamide.

31. (previously presented) A process as claimed in Claim 27, wherein the etherified β -cyclodextrin used is Hydroxypropyl Beta Cyclodextrin.

32. (previously presented) A process as claimed in Claim 31, wherein the molar substitution of Hydroxypropyl Beta Cyclodextrin is from about 0.5 to about 1.2.

33. (canceled).

34. (previously presented) A process as claimed in Claim ~~33~~27, wherein said oxazaphosphorine antineoplastic content is from about 25 mg/ml to about 750 mg/ml.

35. (previously presented) A process as claimed in Claim 34, wherein said oxazaphosphorine antineoplastic content is from about 50 mg/ml to about 500 mg/ml.

36. (previously presented) A process as claimed in Claim 35, wherein said oxazaphosphorine antineoplastic content is about 50 mg/ml.

37. (previously presented) A process as claimed in Claim 35, wherein said oxazaphosphorine antineoplastic content is about 500 mg/ml.

38. (canceled).

39. (currently amended) A process as claimed in Claim ~~38~~27, wherein the ratio of oxazaphosphorine antineoplastic to mesna is in the range of about 10:1 to about 1:1 on a weight basis.

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40. (previously presented) A process as claimed in Claim 39, wherein the ratio of oxazaphosphorine antineoplastic to mesna is 10:2 on a weight basis.

41. (previously presented) A process as claimed in Claim 39, wherein the ratio of oxazaphosphorine antineoplastic to mesna is 10:6 on a weight basis.

42. (canceled).

43. (currently amended) A process as claimed in Claim ~~42~~27, wherein said etherified β -cyclodextrin content in the composition is about 2.5% to about 40% w/v.

44. (previously presented) A process as claimed in Claim 43, wherein said etherified β -cyclodextrin content in the composition is about 5% to about 20% w/v.

45. (previously presented) A process as claimed in Claim 27, wherein one or more conventional parenteral additives are incorporated into the aqueous solution of Claim 27 step (i) or Claim 27 step (ii) or in water used for making up the volume in Claim 27 step (iii).

46. (previously presented) A process as claimed in Claim 27, wherein said mixture of resultant aqueous solutions is sterilized by filtering through a sterilizing grade filter.

47. (previously presented) A process as claimed in Claim 46, wherein the filtrate from the sterilizing grade filter is aseptically filled into sterile containers and the filled containers are sealed.

48. (previously presented) A process as claimed in Claim 27, wherein the mesna is present as the aqueous solution, and the aqueous solution of step (ii) contains the etherified β -cyclodextrin.

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49. (previously presented) A process as claimed in Claim 27, including in step (iii) the step of making up the volume with water.

50. (previously presented) A stable oxazaphosphorine-containing composition obtainable or prepared by a process as claimed in Claim 27:

51. (canceled).

52. (previously presented) A method of treating a malignant disease comprising administering to a patient suffering said disease an effective amount of a sterile stable oxazaphosphorine-containing composition as defined in Claim 50.